

## REMARKS

Claims 1-11, 21, and 22 are pending in the application. By this Amendment, claims 23-36 are canceled, and claim 1 is amended.

As an initial matter, Applicant wishes to express sincere appreciation to the Examiner for the courtesy extended to Applicant's representative during the personal interview held on November 4, 2004. At the interview, various objections and rejections outstanding in the July 28, 2004 Office Action were discussed in detail. The following remarks reflect subject matter discussed during the interview.

### Objection to Disclosure

In the Office Action, the disclosure is objected to because the BRIEF DESCRIPTION OF THE DRAWINGS section of the specification includes a description of Figure 6 that is not included in the drawings. Applicant respectfully submits that the description of Figure 6 at the top of page 7 of the specification has been deleted by the Preliminary Amendment filed on October 30, 2001. Thus, Applicant respectfully requests reconsideration and withdrawal of this objection.

### Objection to Title

The title of the invention is objected to under 37 C.F.R. § 1.83(a). The Examiner asserts that the title is not descriptive. Although Applicant does not necessarily agree with this assertion, Applicant amended the title to read "ENDOLUMINAL FUNDOPPLICATION DEVICE AND RELATED METHOD FOR INSTALLING TISSUE FASTENER." Thus, Applicant respectfully requests reconsideration and withdrawal of this objection.

### Objection to Drawings

The drawings were objected to under 37 C.F.R. § 1.83(a). The Examiner asserts that the drawings fail to show a light source connected to an endoscope as described in the specification. Applicant respectfully traverses this objection because the drawings clearly show a light source connected to an endoscope. As discussed during the interview, Figs. 3 and 5 each show a light source 3 and 62, respectively, that is connected to an endoscope. Thus, Applicant respectfully requests reconsideration and withdrawal of this objection.

### Rejection Under 35 U.S.C. § 102(e) Based on Kortenbach

Claims 1-4 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kortenbach (U.S. Patent No. 6,068,600). Although Applicant does not necessarily agree with this rejection, Applicant amended independent claim 1 to more clearly define the subject matter recited in that claim. Claim 1, as amended, recites that the closing mechanism is “configured to move in relation to the first and second arms and contact an outer surface of at least one of the first and second arms that faces away from the other of the first and second arms to cause the distal ends of the arms to come together.” As discussed during the interview, Kortenbach does not disclose this recitation. At least for this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

### Rejection Under 35 U.S.C. § 103(a) Based on Kortenbach and Green et al.

Claims 5-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kortenbach in view of Green et al. (U.S. Patent No. 5,554,169). In support of this rejection, the Examiner asserts that “Green et al. discloses a collar (127) configured to

close the jaws" and that "it would [have been] obvious to modify the invention of Kortenbach to include a closing sheath for the purpose of enhanced closing with equal force distribution." For the following reasons, Applicant respectfully traverses this assertion.

Green et al. discloses a surgical stapler 100 including an anvil member 136 pivotally mounted to an elongated housing 134 via a hinge 136C and a tubular collar 127 disposed proximal to the hinge 136C. In operation, as shown in Figs. 15A and 15B, the tubular collar 127 moves distally in the direction of arrow A to force the anvil member 136 to rotate from an open position shown in Fig. 15A to a closed position shown in Fig. 15B. Col. 9, lines 55-58; col. 18, lines 21-37.

Kortenbach discloses a surgical instrument including a grasping and fastening end effector 18 coupled to a distal end 16 of a flexible tube 12. The end effector 18 includes a stationary member 31 and a rotatable fastener head 40 coupled to the stationary member 31, as shown in, for example, Figs. 2 and 3. The fastener head 40 is connected to an actuator 20 via a cable 24, so that the rotational movement of the fastener head 40 can be controlled by the actuator 20. In operation, with the fastener head 40 in an open position (as shown in, for example, Figs. 2 and 11), the end effector 18 is inserted into the stomach 5. When the head 40 is distal of the fundus 7, the head 40 is rotated to the closed position, as shown in FIG. 14.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, the prior art references when combined must teach or suggest all the claim elements. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to modify the reference or to combine reference teachings.

Finally, there must be a reasonable expectation of success. See M.P.E.P. § 2143.

Furthermore, case law in this context indicates that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and that the evidence of a teaching, suggestion, or motivation to combine must be “clear and particular.” As discussed below, the asserted combination of Kortenbach and Green et al. fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

In particular, as to the second criterion, there is no suggestion or motivation in either Kortenbach or Green et al. to combine or modify the asserted teachings of the references in the manner proposed by the Office Action. The Office Action merely asserts that, since Green et al.’s device discloses “a collar (127) configured to close the jaws,” it would have been obvious “to modify the invention of Kortenbach to include a closing sheath for the purpose of enhanced closing with equal force distribution.” However, the asserted motivation is merely a conclusory statement and does not provide any sufficient reasoning as to why “enhanced closing with equal force distribution” would have been desired by one of ordinary skill in the art considering the instrument of Kortenbach, especially when there is no factual evidence indicating that such an asserted modification would result in the “enhanced closing with equal force distribution.”

The asserted motivation may not be the result of impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, one of ordinary skill in the art considering Kortenbach’s instrument would not have been

motivated to employ the collar 127 of Green et al. in the manner suggested by the Office Action since there is no “clear and particular” reason to do so.

For example, the instruments of Kortenbach and Green et al. significantly differ from one another in both structural and operational aspects. In particular, while the arrangement of the anvil member 136 and the collar 127 in Green et al. does not permit rotation of the anvil member 136 in the clockwise direction beyond the position shown in Fig. 15A, the fastener head 40 of Kortenbach permits rotation about 180° with respect to the tube 12. Moreover, while the anvil member 136 of Green et al. opens in the distal direction, the effector 18 of Kortenbach opens in the proximal direction. Given these differences and without the specific teachings disclosed in the present application, there is no clear and particular reason why one of ordinary skill in the art would have been motivated to take Green et al.’s collar 127 and apply it to the Kortenbach’s jaw-closing mechanism.

In addition, the asserted motivation (i.e., for “enhanced closing with equal force distribution”) does not appear to be based on the reference teachings or the knowledge generally available to one of ordinary skill in the art. For example, Green et al. does not teach or suggest that its collar 127 provides the asserted “enhanced closing with equal force distribution.” Nor does it teach, or otherwise suggest, that its collar 127 provides an enhanced closing mechanism as compared to that of Kortenbach.

For at least these reasons, neither Kortenbach nor Green et al. provides any clear and particular teachings to combine their asserted teachings. Thus, Applicant respectfully submits that at least the second criterion for a *prima facie* case of obviousness has not been met.

As to the third criterion, the asserted combination of Kortenbach and Green et al. does not show a reasonable expectation of success because it is unclear as to how the collar 127 of Green et al. could be incorporated into the instrument of Kortenbach. As discussed above, the instruments of Kortenbach and Green et al. significantly differ from each other. Given these structural and/or operational differences, there does not appear to be any reasonable expectation of success in combining the asserted teachings of Green et al. and Kortenbach. For at least this reason, Applicant respectfully submits that the third criterion for a *prima facie* case of obviousness also has not been met.

For at least these reasons set forth above, the asserted combination of Kortenbach and Green et al. fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Therefore, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. § 103(a).

Rejection Under 35 U.S.C. § 103(a) Based on Kortenbach

Claims 10, 11, 21, and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kortenbach.<sup>1</sup>

Dependent claims 10, 11, 21, and 22 depend, directly or indirectly, from independent claim 1. As discussed above, independent claim 1 patentably distinguishes from Kortenbach. Thus, at least by virtue of their dependencies from independent claim 1, claims 10, 11, 21, and 22 are also patentably distinguishable from Kortenbach.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. § 103(a).

Double Patenting Rejection

Claims 5-7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 19 of copending Application No. 10/724,740 (the '740 Application). Applicant respectfully disagrees with this rejection at least because, as discussed during the interview, claims 1-6 and 19 of the '740 Application are not pending in that application. Those claims were canceled at the time of the filing of the '740 Application. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

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<sup>1</sup> In the Office Action, the Examiner identifies the cited reference(s) as "Kortenbach in US Patent No. 5,554,169." While it is unclear what reference(s) is intended by the Examiner, Applicant presumes that the Examiner intended to cite only the Kortenbach reference because Kortenbach is the only reference mentioned in the rejection.

Conclusion

Applicant respectfully requests the reconsideration of this application, the withdrawal of all the outstanding objections and rejections, and the allowance of all pending claims.

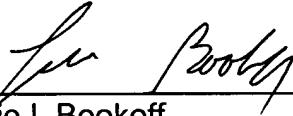
The Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicant declines to necessarily subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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